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Congress of the United States

House of Representatives

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Opening Statement of Rep. Henry A. Waxman
Chairman, Committee on Oversight and Government Reform
Hearing on Safe and Affordable Biotech Drugs — The Need for a Generic Pathway
March 26, 2007

More than twenty years ago, the Congress enacted the Hatch-Waxman Act. That law has taught us three things:

- Generic drugs are good for patients — both medically and financially.
- With a little help, the market works: Generic competition lowers drug prices.
- And generic competition does not bankrupt the brand-name drug industry or slow innovation.

Maybe some big drug makers still dispute these lessons, but no one else does.

But there is still no generic competition for one of the fastest growing and most expensive categories of drugs — biologicals, those drugs produced from living cell cultures rather than from chemical synthesis. Some of these drugs are near-miracles for people with cancer, metabolic diseases, and immune disorders. They can stop disability and — in some cases — save life. People need them.

But some of these drugs cost each patient tens of thousands of dollars a year. Some can cost hundreds of thousands per year. Many people cannot get access to these near-miracles. And even when people can get them, the prices drive up the costs of Medicare, Medicaid, and health insurance overall.

Why isn't the market helping?

It is **not** because of the patent system that biologicals are protected from the competition that might lower prices. Biologicals, like other drugs, do enjoy patent protection. This allows manufacturers to enjoy a monopoly period during which they can get a significant return on their investments. But patents on many of them have already expired, and other patents are just about to expire.

And it is **not** the science of these drugs that protects them from competition. The technology is already here to make safe and effective copies of some biotech drugs. Moreover

the technology is getting better every year, and we can make progress even faster if we allow companies to use it to make generics.

Instead, the monopoly on each of these drugs is perpetuated by the lack of a clear pathway for FDA to approve competing versions. The Hatch-Waxman Act does not reach most of them. This costs all of us — taxpayers, insurance-premium payers, and patients — billions of dollars. It also means that some very sick people simply cannot get the drugs they need.

I know that the science of these drugs is not simple. I take the questions of research, safety, and efficacy very seriously. The only way we can succeed in establishing robust competition for biotech drugs is with drugs that doctors and patients know they can count on. So we need to be sure that the FDA has the discretion to require the studies that are needed to establish that a copy of a biotech drug is equivalent to the brand-name in safety and effectiveness. That's one of the things we hope to learn more about today.

But the big brand-name companies have gone beyond legitimate concern and have thrown up a defensive smoke screen around biologicals. They say there will be problems of safety, decreased innovation, and limited savings. When discussing creating generic competition, they say things like — and I quote:

> "[S]uch action may also save consumers a few dollars here and there, although that is by no means assured. But whatever short-term savings may be achieved will come at an enormous long-term cost to the public .... Focusing solely upon short term lower prices — a 'cheap drugs' policy — will inevitably reduce research and hinder our public health efforts."[1]

These arguments have a familiar ring to them. That's because the words I just read were the formal testimony that the Pharmaceutical Manufacturers Association gave to the House in 1983 when they were opposing Hatch-Waxman. And now manufacturers are using these arguments again.

But they were wrong then. Hatch-Waxman has saved patients billions of dollars and dramatically improved their access to drugs. And Hatch-Waxman did not reduce research or hinder public health.

And they are wrong now. A new path for FDA to approve generic biologicals will save patients billions in the future and will improve access to treatments and cures. And a new path will improve competition, while preserving the market's strong incentives for research.

For the sake of patients, their families, public and private health insurance, and taxpayers, we must find a way to introduce competition to this market. When a patent expires, we owe it to

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[1] House Committee on Energy and Commerce, Subcommittee on Health and the Environment, Statement of the Pharmaceutical Manufacturers Association, *Hearings on H.R. 3605: A Bill that Would Authorize the Food and Drug Administration to Approve Generic Copies of All Pioneer New Drugs,* 98th Cong. 127-131 (Jul. 29, 1983) (Ser. No. 98-67).

consumers to find a way, through competition, to lower prices and still deliver a safe and effective product.

I look forward to the testimony of the witnesses today and learning more about the scope of the problem, the science, and the potential solutions.